Vapor Shark OMB statement 12/7/15:

The PMTA process is an insurmountable hurdle by design, and for good reason. Cigarettes kill nearly half a million people and cost the US $300 billion in economic costs every year. An expensive, onerous and time-consuming PMTA process was put in place to make it harder to introduce new smoking products that are known to kill. The PMTA, however, will paradoxically be the death of the vaping industry. The paradox, of course, is that killing the vaping industry will have the opposite effect on our collective goal and the intended impact of the Family Smoking Prevention and Tobacco Control Act – to prevent smoking and the death and disease associated with it.

My name is Brandon Leidel and I am the founder and CEO of Vapor Shark. I am here to represent my business, and by proxy, to represent the impact that the proposed regulatory framework will have on the vaping industry. Over the course of these meetings, you have no doubt heard from others more qualified than I am to represent vaping's positive impact on public health and its role in the reduction of smoking prevalence. But there are a few undeniable facts that should lay at the bedrock of any discussion on the category, namely:

- Vaping **is** less harmful than smoking.
- Vaping has attracted more smokers more quickly than NRTs, while there is no evidence of a "gateway" effect for non-smokers.
- There are millions of Americans who vape today that no longer smoke cigarettes and I am one of them.

Although e-cigarettes and e-liquids may have the corollary benefit of helping cigarette smokers quit smoking or nicotine use altogether, neither our devices nor our e-liquid products are intended to be smoking cessation devices or nicotine replacement therapies, and are not marketed as such. Rather, our products are legally marketed for recreational use and are intended to compete with tobacco companies. Our goal is to persuade existing adult smokers to make the switch to Vapor Shark's vaping products. Although the available evidence demonstrates that most current e-cigarette users are using these products as an aid to help them quit or cut down on the use of combustible cigarettes, no claims to this effect are being made by Vapor Shark or, to our knowledge, by any of our customers about their products.

Nevertheless, a growing body of research demonstrates without a doubt that vaping is significantly less harmful than smoking and has been used by millions of smokers choosing to make the switch from combustible tobacco cigarettes. Today I have submitted a list of relevant studies for your reference.

Central to vaping's success has been the availability of a wide variety of products to match the varied preferences of a smoker. This is no different than many everyday consumer products

like breakfast cereal, coffee, soda, jeans, alcohol, automobiles, ice cream. - all have hundreds of SKUs to match as many unique consumer preferences. Even cigarettes have over a thousand different products for smokers to choose from. Vaping is no different, its success today and into the future depends on it.
Due to the 2007 grandfather date, virtually every vaping product on the market today would be subject to the onerous and costly PMTA process for approval. As a result, businesses will go bankrupt, people will lose their jobs, and products will come off the market leaving millions of vapers without their preferred alternative to smoking.

I am in a unique position to understand this result. Vapor Shark is a leader in the vaping space and across the vaping ecosystem. As a retailer, franchisor, manufacturer, and distributor, my business touches virtually the entire industry. I can see well beyond the four walls of Vapor Shark.

In five years, we have grown from nothing to over $30 million in annual revenue. We now employ 207 people, 90 corporate employees and 117 through our franchisees, up from 52 just 18 months ago. As a distributor, we support nearly 4000 vaping retailers and manufacturers. We are a growing small business, supporting our industry and our community.

We take our obligation to be leaders in responsible business practices very seriously. Three illustrative examples:

- **Regarding Youth Access:** We have never sold our products to minors and we have put in place rigorous systems to ensure that all of our retail employees and franchisees comply. This includes an industry-first installation of an in-store electronic age verification system, with data retention capabilities. We have been doing this since January of 2012.
- **Regarding product safety:** We were the first business in the industry to require that all e-liquid products sold or distributed by Vapor Shark be tested by a certified 3rd party lab for known harmful substances, including diacetyl and acetyl proprionyl. We then publish the results next to each product on our website and make the results available in-store as well.
- **Regarding Manufacturing Standards**. Vapor Shark manufactures all of our e-liquid in our own lab to ISO standards and with electronic traceability software. We are also members of the American E-Liquid Manufacturing Standards Association (AEMSA). The first and only manufacturer's trade association completely dedicated to creating responsible and sustainable standards for the manufacturing of e-liquids used in e-cigarettes.

To be clear, Vapor Shark, along with many other responsible businesses in our industry, supports, welcomes, and anticipates the regulation of the vaping industry. The standardization

of safety standards, good manufacturing practices, reasonable product testing, appropriate warnings and labeling, child-resistant packaging, and many other science-based regulations that improve public safety are good for our industry and good for current and future consumers of our products.

But the regulation as currently proposed will cripple our industry rather than bolster it.

The PMTA process will bankrupt my business, and the math is simple:

- We sell many SKUs
- Each SKU will require a new application
- Each application is very expensive – particularly the cost of studies necessary to demonstrate the population level "public health" impact of each product.
- The financial burden of each application will cost an estimated $300 thousand to $2 million

I have been warned by advisors both inside and outside the industry that the low-end of this range, provided as a reference point by the FDA, is unrealistic. Others tell me that the uncertainties surrounding the application of this process to my industry make it impossible to estimate.

To explain further: My business manufactures 368 SKU's, all that would be subject to the PMTA. We retail and distribute an additional 2,690 SKUs. I am told that none of them would qualify for Substantial Equivalence as the industry was barely in its infancy in 2007 when any qualifying predicate product would have been on the market.

With an estimated range in cost from $300 thousand to $2 million dollars per application, the result is a broad range of fees that are impossible to comply with. As it stands right now the minimum initial costs would be $110M to well over $730M for the top range of the scale. This is on top of additional ongoing costs associated with managing our innovation pipeline and day to day operations. The **minimum** initial cost alone would cost me well over 3 times our yearly sales total, and I'm told it may cost even more than that.

My business cannot afford that expense, and I am a leader in this space. No manufacturer that I work with can afford it either. There are a half dozen or so companies in our industry that earn between $20 and $50 million, and literally thousands of other smaller businesses rounding out the remainder of the industry. The PMTA process will bankrupt us all. Manufacturers will not have products to wholesale and retailers will not have products to carry. 50,000 people will lose their jobs and a $2B+ industry will disappear. The only exceptions are the Big Tobacco companies, the only billion dollar plus companies that can compete in our space. These companies can survive a PMTA process, or may choose to simply let the industry disappear

completely. Either way, the growing, dynamic category of small businesses and entrepreneurs innovating to continue to improve on a successful alternative to smoking will be gone.

This result is as ironic as it is wrong. Our industry is not only good for the economy, it's good for smokers who desperately seek an alternative. In an open letter to the World Health Organization, 50 leading scientists and public health specialists from 15 different countries call electronic cigarettes a "critical strategy" to prevent tobacco-related deaths. They refer to e-cigs as being "among the most significant health innovations of the 21st Century – perhaps saving hundreds of millions of lives." Yet the very body tasked to prevent the death and disease caused by smoking is poised to snuff out its best chance.

Advisors, attorneys, and my colleagues in the industry have compiled a set of relevant suggested alternatives to the FDA's current proposal that may avoid the result I've just described. I do not claim to be an expert in federal rulemaking, but have nevertheless submitted a compilation of these alternative approaches and hope that they can be useful in your process.

There are a number of legal, common-sense measures that FDA can take.

For example, FDA has the authority and an obligation to promulgate regulations that make sense and protect the public health. A couple of ideas to consider is (1) amending the Grandfather Date for deemed products, and (2) creating a more simplified, streamlined PMTA process for new products.

Regarding the Grandfather Date, FDA not only has the enforcement discretion to amend the Grandfather Date for deemed products, but an affirmative obligation to do so based on Congress' intent in creating the Tobacco Control Act. The only appropriate Grandfather Date for these products is the effective date of the Deeming Regulation.

Additionally, the notion that the PMTA is necessary to protect the public health is false. FDA has the authority to prevent adulterated and misbranded products from being sold without retroactively applying the PMTA to the current market. For new products introduced after the effective date of the Deeming Regulation, FDA should create a streamlined/expedited PMTA process for e-liquids and e-cigarette devices, considering their vastly different risk profile compared to combustible tobacco products. This streamlined process would remove the burden of the population-level analysis from individual companies like Vapor Shark. Rather, FDA should use its enforcement discretion and perhaps its notice and comment rulemaking authority and find that the *category* of e-vapor products are "appropriate for the protection of the public health" as long as they can show they are not targeting minors or non-smokers. FDA can initiate a separate rulemaking process to determine whether the category of products meets this requirement. These are just a couple of ideas for OMB and FDA to consider.

So on behalf of my company, my customers, and my industry, I ask that you please consider the practical and devastating impact that the current PMTA process will have on our industry. Recognizing that a process designed to make it harder to introduce deadly new smoking products would in fact have the opposite effect by wiping out an effective alternative to smoking.

Thank you.

Brandon Leidel
President
Vapor Shark